DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region d1696

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6005

July 27, 1998

WARNING LETTER

Mr. Daniel Cohen, President
Atlantic Cape Fisheries, Inc.
985 Ocean Drive
Cape May, New Jersey 08204

File No.: 98-NWJ-31
CFN: 2245692

Dear Mr. Cohen:

An investigator of the Food and Drug Administration conducted an inspection of your seafood processing operation on May 21 and 22, 1998. At the conclusion of the inspection, Mr. Peter Hughes, General Manager was presented with Inspectional Observations Form FDA-483 listing serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 110. This section covers the Good Manufacturing Practice in Manufacturing, Holding, and Packing Human Food. By virtue of these deviations, the seafood products processed at your facility are adulterated within the meaning of Section 402(a)(4) of the Food, Drug and Cosmetic Act (the Act).

Specifically, our investigator found that the seafood processing area was not equipped with a readily accessible toilet facility as required in Section 110.37(d), or a hand-washing facility as required in Section 110.37(e).

In addition, the inspection found serious deviations from FDA's seafood processing regulations (21 CFR Part 123). The seafood processing regulations, which became effective on December 18, 1997, require that you implement a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HAACP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur. These are the kinds of measures that prudent processors already take. HACCP provides a systematic way of taking those measures that demonstrates to us, to your customers, and to consumers, that you are routinely practicing food safety by design. Seafood processors that have been fully operating HACCP systems advise us that they benefit from it in several ways, including having a more safety oriented workforce, having less product waste, and having fewer problems generally.

The FDA investigator observed shortcomings in your system that, upon preliminary review, appear to be deviations from the

principles of HACCP and the significant requirements of the program. In addition to the Form FDA-483, the FDA investigator provided you with a copy of the Domestic Seafood HACCP Report (Form FDA-3501) which presents her evaluation of your firm's performance regarding various aspects of the HACCP and GMP requirements. The observations of concern to us are as follows:

1) Your firm does not meet the requirements of 21 CFR 123.6.(a) in that hazard analyses were not conducted for any fish products which include tuna, mackerel, squid, mahi-mahi, tautog, bonito, black sea bass, bluefish, trout, and shad.

2) Your firm does not meet the requirements of 21 CFR 123.6(b) in that HACCP plans were not prepared for the processing of products such as tuna, mahi-mahi, bonito, bluefish, shad, and mackerel which are susceptible to significant food safety hazards such as histamine formation.

3) Your firm does not meet the requirements of 21 CFR 123.6(c) in that processing times and temperatures are not monitored and recorded for these fish. It was noted that only the temperatures of incoming fish were recorded.

4) Your firm does not meet the requirements of 21 CFR 123.8 in that:

   a) The records of the temperatures of incoming fish are not reviewed.

   b) Verification activities do not include the calibration of the digital thermometer used to measure the temperature of the fish.

   Records of these activities must be reviewed by an individual who has successfully completed training in the application of HACCP principles in accordance with 21 CFR 123.10.

5) Evaluation of your plant sanitation found that your firm is not meeting the requirements of 21 CFR 123.11 in that:

   a) Sanitation monitoring operations were not recorded for a majority of the operating days during the period January 1998 to May 1998.

   b) Equipment used to manufacture the ice utilized for packing fish products was noted to have a yellowish-white film on tubing and plexi-glass doors that come into contact with the ice.

   c) Numerous flies were noted in the processing area.

Atlantic Cape Fisheries, Inc.
Cape May, New Jersey 08204

We recommend that you develop and implement written sanitation standard operating procedures that provide specific guidance on how and when to perform the sanitation related activities, which must be monitored by your firm.

Please notify this office within 15 working days after receipt of this letter of the specific steps you have taken to correct the violations, including the explanation of each step being taken to prevent recurrence. Failure to correct these violations as proposed may result in regulatory action without further notice.

If you disagree with FDA's preliminary assessment, you should explain how your system identifies hazards and implements controls in a manner that the agency should regard as complying with the regulations. We understand that HACCP systems may be uniquely tailored to meet the circumstances of the individual processor and that there may be more than one right way to control hazards.

Your reply should be directed to the Food and Drug Administration, New Jersey District Office, 10 Waterview Boulevard, Third Floor, Parsippany, New Jersey 07054, Attention: Richard T. Trainor, Compliance Officer.

Sincerely yours,

Douglas Ellsworth

DOUGLAS ELLSWORTH
District Director
New Jersey District

CERTIFIED MAIL -
RETURN RECEIPT REQUESTED

RTT